14 October 2021
EMA/CHMP/555194/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cibinqo

abrocitinib

On 14 October 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cibinqo, intended for the treatment of atopic dermatitis.

The applicant for this medicinal product is Pfizer Europe MA EEIG.

Cibinqo will be available as 50 mg, 100 mg and 200 mg film-coated tablets. The active substance of Cibinqo is abrocitinib, a Janus kinase (JAK)1 inhibitor (ATC code: D11AH). JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor receptor interactions on the cellular membrane, influencing cellular processes of haematopoiesis and immune-cell function.

The benefits of Cibinqo are its ability to improve the skin condition as measured by improvements in the Investigator's Global Assessment (IGA) 0/1 and Eczema Area and Severity Index (EASI)-75 response and to reduce itching in patients with atopic dermatitis. The most common side effects are nausea, headache, acne, herpes simplex, increased blood creatine phosphokinase, vomiting, dizziness and upper abdominal pain. The most serious side effects are infections.

The full indication is:

> Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults who are candidates for systemic therapy.

Cibinqo should be prescribed by physicians experienced in the treatment of atopic dermatitis.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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